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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
09 220,691	12 28 1998	NAOKO TSUJI	0327-0759-0	3088

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EXAMINER

WEBER, JON P

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 02 27 2003

33

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/220,691

Applicant(s)

TSUJI ET AL.

Examiner

Jon P Weber, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133)
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 December 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,6 and 22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,6 and 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 31.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Status of the Claims

The response with amendments filed 09 December 2002 has been received and entered. Claims 1,3,4,6 and 22 have now been presented for examination.

Terminal Disclaimer/Double Patenting

The terminal disclaimer filed on 26 December 2002 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US Pat. 6,171,595 has been reviewed and is accepted. The terminal disclaimer has been recorded.

In view of the terminal disclaimer, the rejection over US 6,171,595 is withdrawn.

The argument that In re Braat is appropriate to the instant situation is deemed persuasive. In the instant case, claim 2 of US 6,375,948 is related to instant claim 1 as combination/subcombination. Claim 1 of US 6,375,948 is a new subcombination that cannot be met by the instant claims. Claim 2 was deemed to read on instant claim 1 because of the open "comprising" language. However, US 6,375,948 was later filed, but issued first, hence the Braat analysis holds and two-way distinctness appropriate to combination/subcombination is appropriate. Since the instant application cannot meet the two-distinctness requirement, the double patenting rejection over US 6,375,948 is not sustainable.

Claim Rejections - 35 USC § 112

Claims 1, 3-4, 6 and new 22 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for inhibitors of elastase-like enzymes, does not reasonably provide enablement for inhibitors of elastase like enzymes or neutral endoproteases that are not inhibitors of a matrix metalloproteinase. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and or use the invention commensurate in scope with these claims.

It is argued that the addition of the limitation excluding mercaptopropionamide derivatives is sufficient to overcome the rejection. New claim 22 reinstates the phosphonates that were canceled with the amendment of 01 February 2002.

A careful rereading of the instant disclosure indicates only two classes of compounds that are specifically identified as classes of compounds that might meet the requirement that the elastase like and neutral endoproteases are inhibited but not MMPs. These two classes of compounds are the mercaptopropionamide derivatives and phosphonic acid derivatives. As indicated in the Office action of 09 August 2002, the mercaptopropionamide derivatives are known to be inhibitors of MMPs. Accordingly, the instant amendment eliminated this class of compounds by negative limitation. Examiner now provides additional evidence that the phosphonic acid derivatives class of compounds are also well-known in the art as MMP inhibitors. See for example: Crimmin et al. (US 5,652,262) at column 1, lines 38-46; Voorhees et al. (US 5,837,224), column 2, lines 31-35; Teronen et al. (US 5,652,227), entire document; Markwell et al. (WO 9115507), entire document; Styczynski et al. (WO 9825580), entire document ; and Collins et al. (US 6,096,730) entire document. Additional relevant references are

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provided with the instant disclosure statement that would be cumulative and are therefore not relied upon.

Inasmuch as the only two classes of compounds specifically identified in the disclosure have been shown to fail to meet the limitations of the instant claims, there do not appear to be any suitable compounds disclosed that meet the stringent requirements of the claims. Given the high degree of unpredictability in finding inhibitors that would exhibit the desired selectivity and the failure to provide guidance on any suitable compounds in the instant disclosure, it would take a considerable inventive contribution to find compounds that meet the selectivity requirements of the claims. Such inventive contribution would not merely be reproducing the work instantly disclosed. It would therefore constitute an undue burden of experimentation.

Applicant's arguments filed 09 December 2002 have been fully considered but they are not persuasive. The rejection under 35 U.S.C. 112, first paragraph is adhered to for the reasons of record and the additional reasons above.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

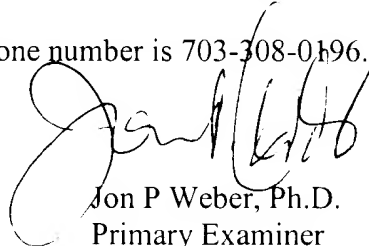
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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon P Weber, Ph.D. whose telephone number is 703-308-4015. The examiner can normally be reached on daily, off 1st Fri, 9/5/4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Jon P Weber, Ph.D.
Primary Examiner
Art Unit 1651

JPW
February 11, 2003